



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Biopesticides and Pollution Prevention Division (7511P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg.  
Number:  
67979-32

Date of Issuance:  
3/21/2017

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:  
Unconditional

Name of Pesticide Product:  
Bt11 x MIR162 x  
MON 89034 Refuge Seed  
Blend Corn

Name and Address of Registrant (include ZIP Code):

Syngenta Crop Protection, LLC - Field Crops - NAFTA  
9 Davis Drive  
Research Triangle Park, NC 27709

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration or registration review of Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn when the EPA requires all registrants of similar products to submit such data.
2. The subject registration will automatically expire at midnight on March 31, 2029.

Signature of Approving Official:

Alan Reynolds, Team Leader  
Microbial Pesticides Branch  
Biopesticides and Pollution Prevention Division (7511P)  
Office of Pesticide Programs

Date:

3/21/2017

3. Make the following labeling change before you release this product for shipment:
  - Revise the EPA Registration Number to read, “EPA Reg. No. 67979-32.”
4. The subject registration will be limited to a seed mix of Bt11 [*Bacillus thuringiensis* Cry1Ab and phosphinothricin acetyltransferase proteins and the genetic material (plasmid insert pZO1502) necessary for their production] x MIR162 [*Bacillus thuringiensis* Vip3Aa20 protein and phosphomannose isomerase protein and the genetic material (plasmid insert pNOV1300) necessary for their production] x MON 89034 [*Bacillus thuringiensis* CryA.105 and Cry2Ab2 proteins and the genetic material (plasmid insert PV-ZMIR245) necessary for their production] field corn seed blended with no less than 5% non-*Bt* corn seed and will have the OECD Unique Identifier: SYN-BTØ11-1 x SYN-IR162-4 x MON-89Ø34-3.
5. Syngenta Crop Protection, LLC - Field Crops - NAFTA (hereafter Syngenta) must commit to do the following Insect Resistance Management (IRM) Program, consisting of the following elements:
  - Requirements relating to a refuge assurance program for ensuring the correct refuge blend percentage.
  - Requirements relating to creation of a non-*Bacillus thuringiensis* (*Bt*) corn refuge in cotton growing areas in conjunction with the planting of any acreage of Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn.
  - Requirements for Syngenta to prepare and require Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn users to sign grower agreements that impose binding contractual obligations on growers to comply with the growing requirements.
  - Requirements for Syngenta to develop, implement, and report to EPA on programs to educate growers about IRM for seed blends.
  - Requirements for Syngenta to develop, implement, and report to EPA on monitoring programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to the Cry1Ab, Vip3Aa20, Cry1A.105, and Cry2Ab2 proteins in the target insects.
  - Requirements for Syngenta to develop, and if triggered, to implement a remedial action plan that would contain measures the company would take in the event that any field-relevant insect resistance to Cry1Ab, Vip3Aa20, Cry1A.105, and Cry2Ab2 was detected, as well as to report on activity under the plan to EPA.
  - Requirements for Syngenta to make available to the Agency upon request records of the number of units of Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn sold or shipped and not returned, and the number of such units that were sold to persons who

have signed grower agreements for the previous growing season, within three months of the request.

- Requirements for Syngenta, on or before August 31<sup>st</sup> of each year, to submit reports on Cry1Ab, Vip3Aa20, Cry1A.105, and Cry2Ab2 resistance monitoring.
  - Bag Tag Requirements for Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn. Seed bags and/or bag tags for corn hybrids that contain plant-incorporated protectants produced in Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn must display the registration number and active ingredients, and stipulate that growers read the Syngenta Stewardship Guide (or equivalent guidance) prior to planting these hybrids. The refuge size requirement must be displayed on the bag or bag tag in both text and graphic format.
6. Implement the following Insect Resistance Management (IRM) Program for Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn:

**a) Corn-Belt/Non-Cotton Growing Areas**

Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn contains a Lepidopteran refuge that is “in the bag” and is automatically implemented when the grower plants the product. No additional refuge is required when planting this product.

Foliar insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, beet armyworm, dingy cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, stalk borer and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

**b) Cotton-Growing Region Refuge Requirements**

In cotton-growing regions where corn earworm is a significant pest:

- A 20% refuge must be planted with non-*Bt* corn hybrids.
- Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn and the 20% non-*Bt* refuge should be sown on the same day, or with the shortest window possible between planting dates.
- External refuges may be planted as an in-field or adjacent (e.g., across the road) refuge or as a separate block within 1/2 mile of the Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn field.
- In field refuge options include: blocks, perimeter strips (i.e., along the edges or

headlands), or in-field strips.

- When planting the refuge in strips across the field, refuges must be at least four (4) rows wide.
- Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, beet armyworm, dingy cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, stalk borer and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial *Bt* insecticides must not be applied to non-*Bt* corn refuge plants.
- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).
- When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance must be provided by Syngenta to help these growers meet the refuge requirements across their farming operations.

**c) Grower Agreements for Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn**

1. Persons purchasing Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn must sign a grower agreement. The term grower agreement refers to any grower purchase contract, license agreement or similar legal document.
2. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
3. Syngenta must integrate this registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn will affirm

annually that they are contractually bound to comply with the requirements of the IRM program.

4. Syngenta must integrate this registration into the current system used for its other *Bt* corn plant-incorporated protectants, which is reasonably likely to assure that persons purchasing Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn sign grower agreement(s).
5. Syngenta shall maintain records of all Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn grower agreements for a period of three (3) years from December 31<sup>st</sup> of the year in which the agreement was signed.
6. Syngenta shall make available to the Agency upon request records of the number of units of Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn seed sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements for the previous growing season, within three months of the request.
7. Syngenta must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license numbers of the growers, will be protected.

**d) IRM Education and Compliance Monitoring Programs for Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn**

1. Syngenta must implement and enhance a comprehensive, ongoing IRM education program designed to convey Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn users the importance of complying with the IRM program. The program must also address unexpected pest damage and guidance for growers in this area. The education program shall involve the use of multiple media, *e.g.* face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements and specifically the need to plant a lepidopteran refuge in cotton growing regions. Syngenta shall coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.
2. Syngenta must conduct targeted, on-farm compliance assessments for growers who purchase Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn seed to ensure

growers are compliant with the requirement of a 20% refuge for lepidopteran pests in cotton growing areas. Results of these on-farm surveys must be reported separately from non-seed blended products.

Syngenta must provide, in conjunction with other Syngenta PIP products, a report to EPA summarizing the Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn compliance assurance program activities and results for the prior year and plans for the Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn compliance assurance program for the current year, annually by January 31<sup>st</sup>. Within one month of submitting this report to EPA, Syngenta shall meet with EPA to discuss its findings. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements.

3. Syngenta shall implement and enhance its education program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
4. Syngenta must maintain and provide to the Agency upon request, substantive changes to educational programs within three months of the Agency's request.
5. Syngenta shall revise and expand its existing Compliance Assurance Program to include the following elements: Syngenta must prepare and submit a written description of its revised Compliance Assurance Program. Syngenta may coordinate with other registrants in designing and implementing its Compliance Assurance Program.
6. Syngenta will enhance the refuge education program throughout the seed delivery channel to:
  - i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;
7. Syngenta will focus the majority of on-farm assessments on regions with the greatest risks for resistance:
  - i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
  - ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions where Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn is used.
8. Syngenta will use its available Bt11 x MIR162 x MON 89034 Refuge Seed Blend

Corn sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:

- i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn but may have purchased little or no refuge seed from the registrant, licensee, or affiliated companies.
  9. Syngenta will contract with third parties to perform on-farm assessments of compliance with refuge requirements:
    - i. A third party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.
    - ii. The third-party assessors will conduct all first-time on-farm assessments for as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment.
  10. Syngenta will annually refine the on-farm assessment program for the Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn to reflect the adoption rate and level of refuge compliance for Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn.
  11. Syngenta will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:
    - i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two years by Syngenta, a seed supplier, or a third party assessor, after completing the assessment process;
    - ii. Syngenta will conduct follow-up checks on growers found to be significantly out of compliance within three years after they are found to be back in compliance;
    - iii. A grower found with a second incident of significant non-compliance with refuge requirements for Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn within a five-year period will be denied access to Syngenta's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.
- e) **Insect Resistance Monitoring and Remedial Action Plan for Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn**

**EPA is imposing the following conditions for Cry1Ab, Vip3Aa20, Cry1A.105, and**

**Cry2Ab2 toxins expressed in Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn:**

Syngenta will monitor for resistance to its lepidopteran-resistant *Bt* corn. The monitoring program shall consist of three approaches: (1) focused population sampling and laboratory testing; (2) investigation of reports of less-than expected control of labeled insects; and (3) should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented.

**(1) Focused Population Sampling**

Syngenta shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to lepidopteran resistant *Bt* corn and/or changes in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* corn. The Agency shall be consulted prior to the implementation of such modifications.

Syngenta will report to the Agency before August 31<sup>st</sup> each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the *Bt* protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results



of these shall be reported to the Agency annually before August 31<sup>st</sup>. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt* corn hybrids under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.
3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:
  - Determining the nature of the resistance (*i.e.*, recessive or dominant, and the level of functional dominance);
  - Estimating the resistance-allele frequency in the original population;
  - Determining whether the resistance-allele Frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
  - Determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, Syngenta will consult with the Agency to develop and implement a case-specific resistance management action plan.

## **(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:**

Syngenta will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. Syngenta will instruct its customers to contact them if such incidents occur. Syngenta will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), Syngenta will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

*Suspected resistance*

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- The corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- The seed used had the proper percentage of corn expressing *Bt* protein;
- The relevant plant tissues are expressing the expected level of *Bt* protein; and
- It has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt* corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, Syngenta will instruct growers to do the following:

- Use alternative control measures in the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, Syngenta will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

*Confirmed resistance*

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited

to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of  $\geq 0.1$  in the sampled population.

- In standardized laboratory bioassays, the  $LC_{50}$  exceeds the upper limit of the 95% confidence interval of the  $LC_{50}$  for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

### **(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field**

When field resistance is *confirmed* (as defined above), the following steps will be taken by the registrant:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;
- Syngenta will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. Syngenta will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g. growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the

resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31<sup>st</sup> each year for the duration of the registration.

**f) Refuge Assurance Program for Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn**

Syngenta must implement a Blended Seed Refuge Assurance Program designed to ensure Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

1. Trait purity check on seed lots prior to blending;
2. ISO certified Standard Operating Procedures for the blending process;
3. Calibration of blending equipment; and
4. Records and data retention records for seed blend products.
  - Calibration records – Syngenta will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results.
  - Blend proportion records (weight and kernel based) - Syngenta will retain documentation for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up an Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn product by seed lot.

All records must be maintained at the Syngenta blending facility and must be available for the EPA review upon request.

**g) Annual Reporting Requirements for Bt11 x MIR162 x MON 89034 Refuge Seed Blend Corn**

1. Compliance Assurance Program: compliance assurance program activities, including IRM Grower Survey and on-farm assessment results for the prior year and plans for the compliance assurance program for the current year, on or before January 31<sup>st</sup> each year;
2. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31<sup>st</sup> each year.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of

statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6. A stamped copy of the labeling is enclosed for your records.

If you have any questions, please contact Wiebke Tapken of my team by phone at (703) 347-0556 or via email at [tapken.wiebke@epa.gov](mailto:tapken.wiebke@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a stylized, flowing script.

Alan Reynolds, Team Leader  
Microbial Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)  
Office of Pesticide Programs

Enclosure

**Plant-incorporated Protectant Label**

**Bt11 × MIR162 × MON 89034 Refuge Seed Blend Corn**

**Alternate Brand Names:**

**Agrisure Viptera® 3330 E-Z Refuge®  
Agrisure Viptera® 3330A E-Z Refuge®**

OECD Unique Identifier: SYN-BTØ11-1 × SYN-IR162-4 × MON-89Ø34-3

**Plant-incorporated protectants:  
Cry1Ab, Vip3Aa20, Cry1A.105 and Cry2Ab2 insecticidal proteins**

This product is effective in controlling corn leaf, stalk, and ear damage caused by corn borers and other  
lepidopteran pests

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**Active Ingredients:**

*Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production  
(via elements of vector pZO1502) in Bt11 corn (SYN-BTØ11-1) .....≤0.017%\*

*Bacillus thuringiensis* Vip3Aa20 protein and the genetic material necessary for its production  
(via elements of vector pNOV1300) in MIR162 corn (SYN-IR-162-4).....≤0.0282%\*

*Bacillus thuringiensis* CryA.105 protein and the genetic material necessary for its production  
(via elements of vector PV-ZMIR245) in MON 89034 corn (MON-89Ø34-3) .....≤0.0333%\*

*Bacillus thuringiensis* Cry2Ab2 protein and the genetic material necessary for its production  
(via elements of vector PV-ZMIR245) in MON 89034 corn (MON-89Ø34-3) .....≤0.00848\*

**Other Ingredients:**

Phosphinothricin acetyltransferase protein and the genetic material necessary for its  
production (via elements of vector pZO1502) in Bt11 corn (SYN-BTØ11-1) .....≤0.000132%\*

Phosphomannose isomerase protein and the genetic material necessary for its  
Production (via elements of vector pNOV1300) in MIR162 corn (SYN-IR162-4) .....≤0.00139%\*

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\*Percent (wt/wt) of whole plant on a dry weight basis

**CAUTION  
KEEP OUT OF REACH OF CHILDREN**

EPA Registration No. 67979-  
EPA Establishment No. 66736-NC-01

Syngenta Seeds, LLC– Field Crops – NAFTA  
9 Davis Drive  
Research Triangle Park, NC 27709

## **DIRECTIONS FOR USE**

It is a violation of federal law to use this product in any manner inconsistent with this labeling.

This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered PIPs that are similarly approved for use in combination to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits. All seed corn containing this PIP must be accompanied by informational material (e.g. a bag tag) indicating the EPA registration number and the active ingredients, and stipulating that growers read the Syngenta Stewardship Guide (or equivalent guidance) prior to planting their seed. The refuge size requirement must be displayed on the seed bag or bag tag in both text and graphic format.

## **Insects Controlled or Suppressed**

Bt11 × MIR162 × MON 89034 Refuge Seed Blend Corn has been genetically transformed to produce the insecticidal proteins Cry1Ab, Vip3Aa20, Cry1A.105 and Cry2Ab2 for control or suppression of the following lepidopteran insects:

European corn borer (*Ostrinia nubilalis*)  
Southwestern corn borer (*Diatraea grandiosella*)  
Southern cornstalk borer (*Diatraea crambidoides*)  
Corn earworm (*Helicoverpa zea*)  
Fall armyworm (*Spodoptera frugiperda*)  
Black cutworm (*Agrotis ipsilon*)  
Western bean cutworm (*Striacosta albicosta*)  
Sugarcane borer (*Diatraea saccharalis*)  
Lesser cornstalk borer (*Elasmopalpus lignosellus*)  
Common stalk borer (*Papaipema nebris*)  
Dingy cutworm (*Feltia jaculifera*)  
Beet armyworm (*Spodoptera exigua*)  
True armyworm (*Pseudaletia unipuncta*)

## **Insect Resistance Management**

Each bag of Bt11 × MIR162 × MON 89034 Refuge Seed Blend Corn contains a blend of 95% Bt11 × MIR162 × MON 89034 seed and 5% non-Bt refuge seed. The following information regarding commercial production of Bt11 × MIR162 × MON 89034 Refuge Seed Blend Corn must be included in the Syngenta Stewardship Guide (or equivalent).

## **IRM Requirements for Corn-Growing Areas of the U.S.**

Refuge seed is blended into each bag of Bt11 × MIR162 × MON 89034 Refuge Seed Blend Corn. There is no requirement for growers to plant a separate structured refuge for managing resistance risk in corn-growing areas of the U.S. Corn-growing areas are those counties and

states not defined below as comprising the cotton-growing areas of the U.S. Read the Syngenta Stewardship Guide or refer to the Table below.

**IRM Requirements for Cotton-Growing Areas of the U.S.**

In cotton-growing areas growers who plant Bt11 × MIR162 × MON 89034 Refuge Seed Blend Corn must plant a supplemental 20% structured refuge. The following table lists those states and counties identified by the Environmental Protection Agency (EPA) as cotton-growing areas.

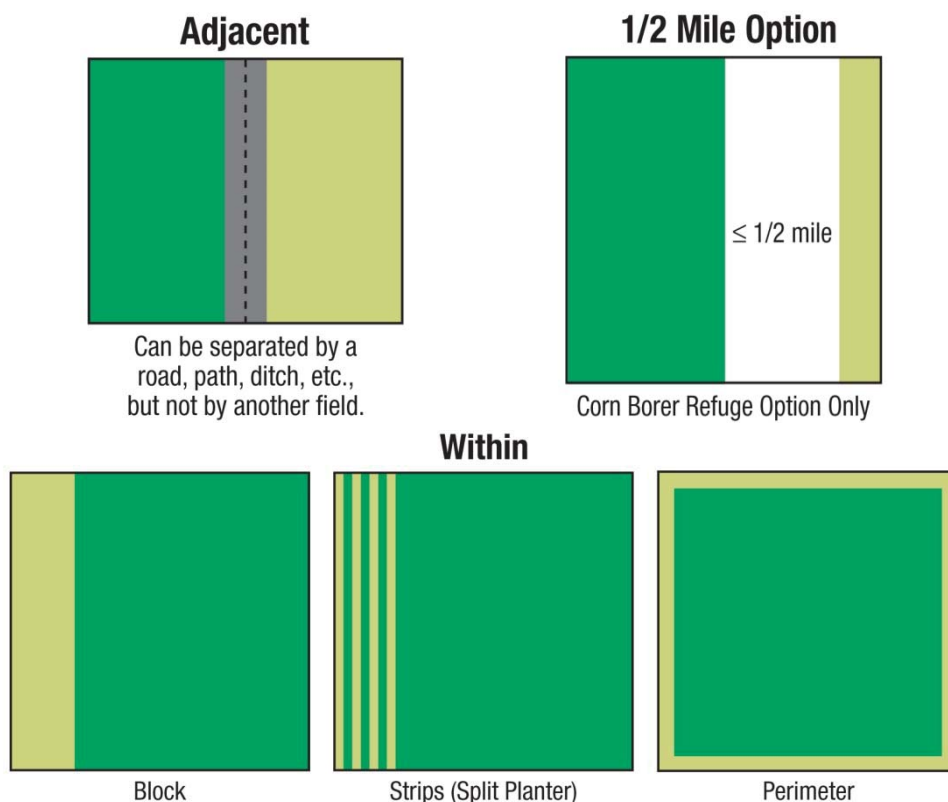
State	Counties Identified by EPA as Cotton-Growing Areas			
Alabama	All Counties			
Arkansas	All Counties			
Florida	All Counties			
Georgia	All Counties			
Louisiana	All Counties			
Mississippi	All Counties			
Missouri	Dunklin Stoddard	New Madrid	Pemiscot	Scott
North Carolina	All Counties			
Oklahoma	Beckham Greer Kiowa	Caddo Harmon Tillman	Comanche Jackson Washita	Custer Kay
South Carolina	All Counties			
Tennessee	Carroll Fayette Hardin Lincoln Shelby	Chester Franklin Haywood Madison Tipton	Crockett Gibson Lake Obion	Dyer Hardeman Lauderdale Rutherford
Texas	All counties with the exception of the following: Carson Hutchinson Roberts	Dallam Lipscomb Sherman	Hansford Moore	Hartley Ochiltree
Virginia	Dinwiddie Northampton Sussex	Franklin City Southampton	Greensville Suffolk City	Isle of Wight Surrey

The 20% supplemental refuge must be planted with hybrids that do not contain Bt technologies. The supplemental refuge can be planted as strips within the field, perimeter strips, a block within the field, a block adjacent to the field, or a separate block within ½ mile of the Bt11 × MIR162 × MON 89034 Refuge Seed Blend Corn field. If in-field or perimeter strips are planted, the strips must be at least four consecutive rows wide.



The supplemental refuge in cotton-growing areas can be protected from feeding damage by application of non-Bt microbial insecticides if the population of one or more lepidopteran pests exceeds economic thresholds. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents or crop consultants). In addition, the supplemental refuge can be protected from corn rootworm feeding damage by use of an appropriate seed treatment or conventional insecticide.

The following are schematics of the various refuge deployment options:



The following text and graphic indicating the supplemental refuge size requirement will appear on Bt11 × MIR162 × MON 89034 Refuge Seed Blend Corn bags or bag tags.

**Important grower information.  
Supplemental refuge planting requirement.**



**For more information, please refer  
to Syngenta Stewardship Guide.**